

Remarks

Claims 7-10 were rejected under 35 U.S.C. 112, first paragraph, as being based on a disclosure which is non-enabling. Claim 7 describes imaging treated tissue to provide images representing one or more sections of the treated tissue. 35 U.S.C. 112, paragraph six, states that “[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof.” So long as such imaging is enabled by the FIGS. 1-3 of the present application as well as the specification at pages 4-12, Claim 7 meets the requirement of 35 U.S.C. 112, first paragraph. To state otherwise would obviate and be contrary to 35 U.S.C. 112, paragraph six, of the ability to draft a method step without recitation of structure, material or acts, as the Examiner appears to require. The Examiner states a critical feature is not claimed, but the critical feature of the invention is indeed described, i.e., the imaging of one or more sections.

In the case of In re Mayhew, 188 USPQ 356 (CCPA 1976) cited by the Examiner in support the rejection, a cooling step at a particular zone in a process was absent in the claims (see 188 USPQ 357). This is not the case here where there are no absent steps in method Claim 7. Clearly, Claim 7 is sufficiently enabling under 35 U.S.C. 112, first paragraph, and no additional elements are necessary. Accordingly, withdrawal of the 35 U.S.C. 112, first paragraph, rejection is requested.

Claims 7-10 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable imaging tissue section(s) by another modality than confocal microscopy. It is well established in patent jurisprudence that so long as the specification described has at least one enabling embodiment, 35 U.S.C. 112, first paragraph, is satisfied, and additional embodiments are not required. It is clearly evident that at least one embodiment for imaging tissue is provided by FIGS. 1-3 and by the specification at pages 4-12 (see MPEP 2164.01). As MPEP 2164.01(b) states:

[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enabling requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1734 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987).

Accordingly, withdrawal of the 35 U.S.C. 112, first paragraph, rejection that additional modalities be disclosed is requested.

Claims 7-10 were rejected under 35 U.S.C. 102(b) as being anticipated by International Publication No. WO 95/03089 (Zavislan). Zavislan does not provide an image representing one or more sections of tissue, as described in Claim 7. Zavislan uses a video camera which does not enable view of a section of the tissue. To clarify this, rather than to overcome any rejection, Applicants have amended Claim 7 to describe at least one of the images as capable of being a section at a depth under the surface of the tissue. Clearly, Zavislan fails to disclose such capability. Therefore Zavislan cannot anticipate Claims 7-10, and withdrawal of this rejection is requested.

Claims 7-10 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,034,613 (Denk et al.) "Denk". Claim 7, as amended, describes images from light reflected from the tissue. Denk lacks the ability to detect reflected light. Dichroic mirror 28 (FIG. 1) of Denk prevents reflected light from reaching its detector 54. Denk relies on two-photon absorption and fluorescence to produce an image from the object of interest (see Denk at column 4, line 61, to column 5, line 39). Accordingly, Denk cannot anticipate Claims 7-10, and withdrawal of this rejection is requested.

Claims 7-10 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,200,838 (Nudelman et al.) "Nudelman". Nudelman does not provide an image representing a section of tissue, as described in Claim 7. Nudelman's three-dimensional image of an object is not comparable to an image of section of an object. If Nudelman were capable of imaging a section, it would include means for limiting light to a particular focal length in tissue. Even Nudelman's statement regarding confocal laser microscopy is based on providing "multiple focal layers of the specimen" for "three dimensional image reconstruction", which teaches away from using imaging to provide an individual focal layer such as indicative of an image of a section (see column 7, lines 64-66).

Each of the photosensors of Nudelman merely image either the specular surface, or the bulk properties of a volume of tissue without any restriction of the light to a section. Nudelman by teaching the use of two or more spaced lateral effect diode detectors to acquire image signals to produce three-dimensional images, actually teaches

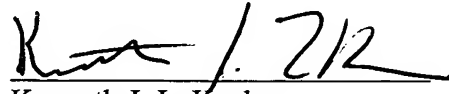
away from limiting image signals from its detectors to a section of the object (see Nudelman at columns 10-12). Nudelman's objective is to facilitate the derivation of stereo pairs and three-dimensional imaging of the surface to be imaged (see column 5, lines 39-41). Thus, Nudelman's three-dimensional images are merely intended to be contour maps of the tissue surface, not sectional images. The construction of tomographic planes mentioned at column 12, lines 45-50 using different wavelengths, does not state that Nudelman generates a section. The photosensors may image a volume from the tissue surface to a depth in the tissue dependent on wavelength, but such imaged volumes do not resolve sections. Nor do wavelength dependent images when processed, represent the optical properties in a section of the volume. The heterogeneous nature of tissue volumes imply that "the depths of penetration below the surface of an object" (column 12, line 49) may or may not represent a continuous surface let alone a section. Light penetration from the optical system into an object and its return to the optical system represents a diffusion process dependent on optical properties above and below a structure of interest. As Nudelman indicates multispectral illumination can enhance contrast of a particular structure, say a blood vessel; however, such an image would not represent a surface containing the blood vessel and adjacent tissue. In fact, without true sectional imaging, multispectral contrast enhancement attempts to make certain structures less visible in order to make other structures more visible. True sectional imaging picks a focal layer of interest and preferentially collects light from that layer. Thus, withdrawal of the rejection of the claims as being anticipated by Nudelman is requested.

Claims 7-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,035,693 (Kratzer et al.) "Kratzer". Kratzer does not describe or suggest an image representing a section of tissue of amended Claim 7. As the abstract of Kratzer describes "cells are arrayed in a plane for successive illumination". This is evident in FIGS. 3 and 4 of Kratzer where the imaging plane is the surface of a belt (column 5, line 23) or the surface of a transparent plate (column 5, lines 30-31). Thus, Kratzer does not need any capability for sectional imaging, since the cells are already in a plane when scanned. Accordingly, Claims 7-9 cannot be obvious in view of Kratzer, and withdrawal of the 35 U.S.C. 103(a) rejection of these claims is requested.

New Claims 12-13 are added for consideration by the Examiner. Claim 10 was amended due to language added to its base Claim 7.

It is believed the Application is in condition for allowance. A petition for a three-month extension of time is enclosed with a check for the required petition fee of \$510.00.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'K. LuKacher', followed by a horizontal line.

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Enclosures: Combined Amendment and Petition for a three-month extension of time  
with a Check for \$510; and  
Certificate of Express Mailing, Express Mail No. EV 586785148 US